

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF TEXAS - FORT WORTH DIVISION**

**JAMES SHEPHERD, et al.,**

*Plaintiffs,*

v.

**ENVIRONMENTAL PROTECTION AGENCY, et al.,**

*Defendants.*

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**CIVIL CAUSE NO.  
4:23-cv-826**

**PLAINTIFFS' REPLY IN SUPPORT OF APPLICATION FOR PRELIMINARY  
INJUNCTION AGAINST THE ENVIRONMENTAL PROTECTION AGENCY**

Plaintiffs herein reply to the EPA's *Defendants' Response in Opposition to Plaintiffs' Amended Motion for Preliminary Injunction* (Doc. 17) and *Memorandum in Support* (Doc. 18, together "Response"). Plaintiffs incorporate their *Amended Complaint* ("Complaint"). The EPA argues in its Response that Plaintiffs cannot show: a) third-party standing; b); success on the merits; c) irreparable harm; and d) public interest and balance of equities support.

Plaintiffs show their licensing agreements convey standing. Further, the EPA's actions are causing irreparable harm to Plaintiffs by destroying their supply chain using stop orders which are arguably directed to Plaintiffs' entire supply chain, threatening them with bankruptcy, causing market loss, and significantly harming the JBS Trust property. Plaintiffs further show they are likely to succeed on the merits because Berkey's filters have no "substances" intending to kill pests and thus not pesticides. Plaintiffs here object to the EPA's new enforcement approach, adopted without notice and used to shut down the sale of filters sold for more than 20 years without an issue while making *mechanical* pesticidal claims without EPA interference. The EPA must first comply with the APA's rule-making process, and cannot justify its actions based on a random statement on a European website discussing the use of silver to protect the filter.

Because the EPA failed in its Response to show sufficient justification for its stop orders, this Court should enjoin the EPA's arbitrarily and capriciously issued stop orders, which exceed its statutory authority, violate due process and are damaging the livelihood and water quality of thousands of people already, with more being added each day.

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## **I. PLAINTIFFS' REPLY TO EPA RESPONSE<sup>1</sup>**

1. According to the law and legislative history, EPA cannot use FIFRA to regulate water filters as pesticides. By extension, the EPA's stop orders<sup>2</sup> are invalid for not having proper statutory authority. Even if the EPA could regulate water filters under FIFRA and the APA, Berkey products still do not meet the definition of a pesticide because they use a mechanical maze of filtrates that capture and hold and do not destroy any pests. The silver in the filter does not dissolve in the water and is not used as a pesticide. Further, the stop orders cite *non-pesticidal* claims by foreign parties not under the jurisdiction of the EPA, without using any statements from the stop order recipients, to excuse the EPA's overreach.

2. To the extent the EPA wishes to claim that Berkey products are a pesticide, the basis for the stop orders fails because they are predicated on a policy interpretive rule which negatively effects Plaintiffs' rights without the opportunity to receive notice and comment as required by the Administrative Procedures Act ("APA"). Contrary to the APA, no change in the EPA's enforcement rules has been announced. The EPA's excuse that it found out that silver is used to protect the filters cannot be justification for shutting down a quarter-century old company with well-established products upon which tens of thousands of people depend, on the whim of a small number of rogue agents.

### **A. Plaintiffs have standing in their own right and third-party standing on behalf of their business affiliates which have received stop orders and their end user clients.**

#### ***i. Plaintiffs have standing based on damage they have suffered.***

3. Plaintiffs sue to protect their own rights from irreparable harm done by the EPA. *See* Doc.

14. Plaintiff James Shepherd has fiduciary duties as trustee to Plaintiff JBS Trust to protect the

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<sup>1</sup> This Plaintiffs' Reply is limited to arguments pertaining to injunctive relief in Defendant's response. Plaintiff reserves all arguments for declaratory relief, and any other relief to which they are entitled.

<sup>2</sup> The full name is "Stop Sale Use or Removal Order" and also abbreviated as "SSURO" in many documents.

trust property and purpose, which has been harmed by the EPA's stop orders. *See* Doc. 14-1. Plaintiffs believe they are immanently imperiled by the EPA's ongoing march of stop orders issued against its vendors and sales channel partners, and continuing without resolution will result in an inability to distribute Berkey products in the US because the EPA would continue issuing stop orders against NMCL. Plaintiffs believed, based on communications from the EPA, that all Berkey affiliated parties have constructive notice of the stop orders and are bound by its instructions. NMCL is clearly a target.

4. Not only are the Plaintiffs damaged through the lost royalty payments in their licensing agreements, but they are also damaged by the never-ending hoops that the EPA is demanding in order to avoid the wrath of EPA agents who are enforcing their whims as though they are federal law. As the Complaint shows at para. 70, one of Plaintiff's vendor is working to establish what kind of packaging for the Berkey products will pass muster. This packaging impacts all sales of all Berkey filter systems. One of the latest demands by EPA inspector Tokarz was that the system boxes not include an image of a lake, ostensibly because that equates to a message that Berkey filters can remove pests from lake water.<sup>3</sup> There appears to be no end to the ways in which the EPA can restrict Berkey filter sales. *See* Doc. 14 and attachments. The EPA's attack on Berkey products is being used as a cudgel by competitors while the public is damaged by a lack of Berkey products due to the EPA's destructive approach to regulation where no problem exists. *Id.*

5. Additionally, the Court is allowed to make natural inferences on alleged facts. As stated, the EPA is in the process of attacking every organization involved in distributing Berkey-marked products. If it is successful, the registered marks can be found to be abandoned and canceled from the USPTO's registry. Other competitors could then use the mark at will. Thus, the JBS Trust is

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<sup>3</sup> Berkey products have often stated that its filters can purify lake water, but this last exchange was after that verbiage was set for removal. The EPA refuses to give direction as to what packaging might pass.

imperiled with irreparable harm if its trademarks are disused, as a competitor could start using the marks and claim they were abandoned if the JPB Trust is unable to resume sales under that name.

6. The EPA also seems to misunderstand the relationship amongst the parties. As the Declaration of James Shepherd (Doc. 13-1) states, Plaintiff JBS Trust holds the intellectual property concerning Berkey products, and receives royalties on the sale of filters sold by NMCL and Berkey Int'l. NMCL uses Berkey Int'l as a master distributor. A stop order against Berkey Int'l thus eliminates supply of materials and systems to sell, sales channel wide, damaging both Plaintiffs by eliminating activity through Plaintiff's master distributor. Doc. 13-1.

7. Based on these relationships, Plaintiffs have standing to vindicate their own rights, with Jim Shepherd suing as trustee to protect the JBS Trust property, and NMCL as plaintiff for the harm it is suffering due to lost product availability due to the EPA's stop orders. Further, NMCL cannot distribute its Berkey products as they will be targeted for a stop order and registration requirements for the same erroneous reasons. *See* Doc. 14. Because EPA agent Tokarz has effectively stated that anyone with knowledge of the stop orders and seeking to go around them could be considered to be acting in violation of these orders. *Id.* Thus, both Plaintiffs have their own standing in this case.

8. As other courts have found, "An injury is traceable if there is a causal connection between the injury and the conduct complained of by the plaintiff. While the defendant's conduct need not be the last link in the causal chain, the plaintiff must be able to demonstrate that the alleged harm was caused by the defendant, as opposed to the independent action of some third party not before the court. *Md. Shall Issue, Inc. v. Hogan*, 971 F.3d 199, 205 (4th Cir. 2020).

9. From the statements made by Tokarz and even in the stop orders themselves,<sup>4</sup> even if Berkey products had no labeling whatsoever, and were sold as mere widgets, the EPA might well decide that their reputation as a water purifying device, combined with the non-pesticidal use of silver, justifies a requirement to register as a pesticide. As stated in the Complaint, Berkey Int'l has offered multiple times to revise its labeling, and the EPA has enjoyed turning down labeling, but has refused to give specific rules regarding what might be allowed. Doc. 14-1, pg. 5.

10. Plaintiffs were forced to file this suit hurriedly to stop the EPA from continuing with its zealous attack on a business that has only helped people. Since their initial filing, Plaintiffs have sought to make peace with the EPA. The EPA's agents have refused to relent and have even refused to cease issuing additional stop orders while this suit is pending, making this injunction necessary.

11. At no point have the EPA's agents or representatives offered any solution other than registration of Berkey products as a pesticide or to comply with draconian demands that would end all Berkey product sales. Based on the EPA's own admitted behavior in this case, a completely unrelated business on the far side of the globe, even one that might be controlled by knock-off competitors, could issue a blog post that triggers the EPA into yet another stop order with a comment such as "The silver-using Berkey products are now being sold without labeling, but we all know that this is the same filters that always were great as pesticidal products."

12. In fact, a competitor could do that to every distributor of Berkey products right now, and the EPA would defend its then-issued stop order based on such a blog post, just as it is now doing on the six stop orders issued against Berkey-affiliated businesses that give rise to this case.

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<sup>4</sup> As a reminder, the stop orders combine pesticidal claims made on the labeling of Berkey systems with a statement that silver is used to protect the filter to conclude that the Berkey filter is a pesticide, ignoring the statement about the purpose of the silver. See Doc. 14-2, p. 66, para. 21, 22, and then note the EPA's recitation of FIFRA at para. 7 of that same document, which states a pesticide as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest" (underlining added for emphasis).

13. Even better is the reality that every time a competitor helps the EPA by making such a statement, the EPA can then eliminate that Berkey distributor as a source, and some unregistered, untested knockoff filter gets sold to a desperate consumer who actually needs a quality product, because the EPA is not even trying to stop the sub-rosa operators in the industry.

***ii. Plaintiffs have Third-Party Standing on behalf of its affiliates and customers.***

14. Additionally, Plaintiffs assert that they have standing to act to protect their end customers and Berkey Int'l. The end customers, spread out all over the country, are imperiled by the lack of Berkey filters and be forced to buy knockoffs. Berkey Int'l is located in Puerto Rico, has been effectively put out of business and unable to defend itself.

15. The 10<sup>th</sup> Court of Appeals found third-party standing when the EPA was issuing regulations against the State of Utah, and a business which was going to be damaged filed suit under the APA rules of review. The court there stated, "In a case like this, in which relief for the petitioner depends on actions by a third party not before the court, the petitioner must demonstrate that a favorable decision would create 'a significant increase in the likelihood that the plaintiff would obtain relief that directly redresses the injury suffered.'" *US Magnesium, LLC v. United States EPA*, 690 F.3d 1157, 1166 (10th Cir. 2012) (internal citations omitted).

16. Additionally, in the Fifth Circuit, third-party standing regarding litigation of rights is recognized when the litigant and the third party have a close relationship, and the third-party's exercise of a right is part of the litigant's right. *Richardson v. Tex. Sec'y of State*, 485 F. Supp. 3d 744, 751 (W.D. Tex. 2020).

17. Berkey Int'l certainly has a right under the APA to receive notice that the EPA's long-standing rule that a mechanical filter is not a pesticide remains true until a notice and hearing of the matter occurs. At the very least, a notice should be made so that industry leaders can take note



and provide input. Additionally, Berkey Int'l has a right to know if FIFRA is being enforced in a way that it can anticipate enforcement actions by the EPA which have substantially changed.

18. Similarly, the end users of Berkey filters have a right to know these same changes in rules. The APA does not state simply that notice should be given to major manufacturers – the notices are printed in the Federal Register. Any member of the public may make comment. And with the public, the argument for third-party representation of the end users by the Plaintiffs is stronger because the difficulty of an end user filing suit against the EPA is substantial, and case law recognizes that where practical obstacles prevent a party from asserting rights on behalf of itself, a third party who has sufficient injury-in-fact can serve as a reasonable representative. *Id.*<sup>5</sup>

19. Additionally, as the Plaintiffs argue in their Amended Complaint, consumers during the colonial era could filter water without fear of the newly created government interfering. Plaintiffs therefore assert their Ninth Amendment right to filter water without federal interference, or at the least, as the Court to require Congress to be specific when it is abrogating a right enjoyed from that time by employing the Ninth Amendment as a rule of construction that protects unenumerated rights when a statute is vague.<sup>6</sup>

20. Thus, an injunction from this Court is the only way to stop the EPA's campaign of destruction, to stop the enforcement of the current stop sale orders and pesticide registration requirements against Berkey products, or in the alternative to at least prevent retaliation by rogue players from issuing additional stop sale orders until this case is resolved.

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<sup>5</sup> Third-party standing by a business on behalf of its many consumers is also supported in other circumstances, such as when Twitter quashes subpoenas to it on behalf of its users. *In re Grand Jury Subpoena Issued to Twitter*, No. 3:17-mc-40-M-BN, 2017 U.S. Dist. LEXIS 234352, at \*16-18 (N.D. Tex. 2017).

<sup>6</sup> Plaintiffs realize that this argument is unlikely to succeed at the injunction stage, but that reality is due only to a failure of previous courts to appreciate the Ninth Amendment, and here seek to correct that error.

**B. Plaintiffs are highly likely to succeed on the merits.**

21. The Response argues that they have always regulated mechanical filters that do not contain pesticides to destroy pests as pesticides. Plaintiffs herein show that they are likely to succeed on the merits of their claims because: i) the EPA's sudden decision that a mechanical filter equates to a pesticide is a substantive rule that requires a notice and comment rule-making process governed by the APA; ii) even if the EPA followed the APA and "determined" that a mechanical filter is a pesticide, that conclusion and ensuing regulation would be beyond the statutory authority provided by FIFRA. Plaintiffs statutory and constitutional claims have merit.

***i. The EPA acts arbitrarily and capriciously, in clear error of judgment, exceeding its statutory authority regulating mechanical filters as pesticides.***

22. As stated in the Complaint, the products under the stop orders have always been advertised as mechanical pesticidal products. Also as stated in the Complaint, the filters employ a registered pesticide that is used to protect the filter, and not for a pesticidal effect on the filtered water. The stop orders rely on hearsay statements quoting from foreign websites not under the control of the stop orders recipients.

23. The stop orders will put NMLC out of business and harm the property and thwart the purpose of the JBS Trust. The EPA has given no guidance or notice for its inconsistent actions in clear error of judgment. The public has clearly supported Berkey filters for over a quarter of a century, neither the public interest nor equity serves to allow the EPA to stop businesses producing products that are clearly not a harm to the willing consumers. Berkey products are not pesticides and should not be required to stop production until they register as pesticides, which could take two or more years. Further, Berkey Products exceed NSF/ANSI standards. Enjoining the EPA is necessary to prevent further irreparable harm to Berkey products, Plaintiffs, and Berkey agents.

24. The EPA exceeds its statutory authority under FIFRA for regulating mechanical filters without pesticides as pesticides. If the EPA wants to regulate mechanical filters that do not include any pesticides that destroy pests, they cannot do it under FIFRA.

25. Under FIFRA's definition and the EPA's guidance, mechanical filters that do not incorporate pesticides to destroy pests are not pesticides.<sup>7</sup> The EPA cannot regulate mechanical filters that incorporate an antimicrobial preservative to protect the filter and does not kill any waterborne pests as a pesticide, because FIFRA's definition concerns "substances" and not "materials". *See id.*, and Doc. 13-1. Under the common vernacular, a filter is not a pesticide. Round-Up is a pesticide; carbon filters are not. The dictionary definition of pesticide is "an agent used to destroy pests", which does not include a filtering process to trap and remove waterborne microbes from water.<sup>8</sup> The EPA cannot point to any law, guidance, or legislative history that would allow the EPA to regulate mechanical filters not using any pesticide to destroy pests as a pesticide. The EPA cannot point to any law, guidance, or legislative history that would allow the EPA to regulate mechanical filters not using any pesticide to destroy pests as a pesticide.

26. By extension, the stop order is invalid for not having proper statutory authority. Even if the EPA could regulate mechanical water filters under FIFRA, Berkey products still do not fall under the definitions or guidance of a pesticide. To the extent that the EPA wants to claim Berkey products as a pesticide, that basis for a stop order fails as a policy interpretive rule that affects Plaintiffs' and stop order recipients' rights without notice and comment. *Mack Trucks, Inc. v. E.P.A.*, 682 F.3d 87, 93 (D.C. Cir. 2012) (under the Administrative Procedure Act, the terms or substance of the rule would have to be stated in the notice of hearing, and all interested parties

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<sup>7</sup> U.S. EPA, Pesticide Registration (PR) Notice 2000-1, Notice to Manufacturers, Formulators, Producers and Registrants of Pesticide Products (Mar. 6, 2000); Available at <https://www.epa.gov/pesticide-registration/prn-2000-1-applicability-treatedarticles-exemption-antimicrobial-pesticides> (last visited September 3, 2023).

<sup>8</sup> Available at <https://www.merriam-webster.com/dictionary/pesticide> (last visited September 4, 2023).

would have an opportunity to participate in the rule making; an order in the present case that the respondent was required to obey”). The EPA does not adequately respond regarding this change of enforcement.

27. The rule prior to EPA’s actions starting last year was to refrain from attempting to enforce pesticide regulation against mechanical filters that do not use silver to treat water. If the EPA wishes to change its position, it is required to follow APA rule making notice and comment procedures. The orders never specify if interested parties could give comment, no notice of the orders was published, no notice was given of when a public hearing would take place, nor was any public hearing held at all. All of these are required for notice and comment rulemaking. *See id.*; Doc. 14-2, pgs. 27-70. Neither Plaintiffs nor Berkey agents could be reasonably expected to know that the EPA had changed its enforcement to include mechanical filters in its definition of a pesticide. If the EPA wants to regulate Berkey products as pesticides, the EPA must undergo proper notice and comment procedures before acting on final agency orders through its stop orders. *N.L.R.B. v. Wyman-Gordon Co.*, 394 U.S. 759, 764–65 (1969); *Dorris v. F.D.I.C.*, CIV.A. 93-1659 (RCL), 1994 WL 774535, at \*6 (D.D.C. Oct. 27, 1994); *Env’tl. Def. Fund, Inc. v. Ruckelshaus*, 439 F.2d 584, 594 (D.C. Cir. 1971) (“Not only the legislative history, but also the statutory scheme itself points to the conclusion that the FIFRA requires the Secretary to issue notices and thereby initiate the administrative process whenever there is a substantial question about the safety of a registered pesticide.”); *see also Mack Trucks, Inc.*, 682 F.3d at 95 (D.C. Cir. 2012)(“The question is not whether dispensing with notice and comment would be contrary to the public interest, but whether providing notice and comment would be contrary to the public interest.”).

28. No doubt that the EPA will continue to assert that its enforcement is based on the sudden discovery that Berkey filters uses silver, and it wants to assert that silver is a pesticide, making the entire device a pesticide. But that argument cannot succeed when the statement about silver

actually states the intent of the silver is to protect the filter, and after mountains of paper have been given to the EPA to show that testing has been done to show that the silver does not leach into the water, the EPA cannot argue that its old rule of “mechanical filters are not pesticides even when they are sold with pesticidal claims” has not morphed into “mechanical filters with silver used for any purpose equates to a pesticide.”

29. Because the EPA exceeded its statutory authority, and acted arbitrarily and capriciously, in clear error of judgment, Plaintiffs are likely to succeed on the merits of their claims, showing that the EPA’s new rule is unsupportable and should be enjoined.

***ii. Berkey Products are clearly not pesticides under FIFRA.***

30. The EPA does not have authority to regulate mechanical water filters as pesticides under FIFRA. Berkey Products are mechanical filters that do not destroy pests. Any silver in Berkey Products is a preservative to protect the filter itself, not to treat the water. *See* Doc. 13-1. Berkey products are not pesticides under FIFRA. Berkey products do not destroy pests and still exceed accredited NSF/ANSI standards. Defendants are causing irreparable harm to Plaintiffs and Defendant’s arbitrary and capricious actions should be declared exceeding statutory authority in clear error of judgment and enjoined. The EPA should be enjoined from issuing stop sale orders against Berkey products and pesticide registration requirements against stop order recipients and Berkey products.

31. The EPA alleges Berkey products are pesticides because they are sold with public health claims while using silver for treatment of the filter. *See* Doc. 18. However, Berkey products mechanically trap pests and do not use the silver to kill any waterborne pests. *See* Doc. 13-1, Doc. 14-1, Doc. 14-2, and Doc. 14-4. The EPA’s response only includes conclusory allegations from its “investigation,” which somehow revealed that the public use of silver to protect the filter now makes the entire system a pesticide. *See* Doc. 18, pg. 15.

32. The EPA also attempts to evade Berkey products qualified claims of antimicrobial activity and dodge the issue that Berkey products do not include any pesticide to kill pests.<sup>9</sup>

exemption, known as the Treated Article Exemption. U.S. EPA, Pesticide Registration (PR) Notice 2000-1, Notice to Manufacturers, Formulators, Producers and Registrants of Pesticide Products (Mar. 6, 2000).<sup>7</sup> Public health claims include, *inter alia*, claims “for control of specific microorganisms or classes of microorganisms that are directly or indirectly infectious or pathogenic to man (or both man and animals)”; claims “for the product as a sterilant, disinfectant, virucide or sanitizer, regardless of the site”; or “non-specific claim[s] that the product will beneficially impact or affect public health by pesticidal means at the site of use or in the environment in which applied.” *Id.* at 2-3.

*Pg. 6 of Defendant’s Response (emphasis added)*

33. The EPA’s cited Notice 2000-1<sup>10</sup> lists the public claim in green as #2 on the list, but the EPA has #7 as an option for authority:

7. An unqualified claim of “antimicrobial” activity. Refer to Unit IV.C.

*Notice 2000-1, II, A, 7, pg. 3*

34. The EPA summarizes its “reasons to believe” Berkey made public health claims outside of the treated article exemption, while simultaneously admitting Berkey products use a registered pesticide, inappropriately conflating the two. At this point, the EPA should know better.

35. A mechanical device can be a treated product and not be a pesticide. FIFRA, the actual law Congress wants the EPA to enforce, requires a “substance” that kills pests. Conversely, a product is not a pesticide without a substance fulfilling that role. The element of silver used in a product to

<sup>9</sup> The undersigned apologizes for the repetitive arguments; the goal was to mirror the Response’s arguments.

<sup>10</sup> Available at <https://www.epa.gov/pesticide-registration/prn-2000-1-applicability-treatedarticles-exemption-antimicrobial-pesticides> (last visited September 3, 2023).

protect that product does not turn that product into a pesticide when the element is not used for a pesticidal purpose.

Berkey products were marketed with claims that they “prevent[ed], destroy[ed], or mitigate[ed],” *id.*, viruses and pathogenic bacteria, and they contain antimicrobial silver, a pesticide registered for use on water filters for the pesticidal purpose of eliminating microbes that can grow on the filter, *see supra* p.7. EPA therefore had “reason to believe”—as required for the issuance of a SSURO under 7 U.S.C. § 136k(a)—that Berkey products were pesticides intended for a pesticidal purpose. And because Berkey products are marketed with public health claims about their purported ability to purify water, EPA also had reason to believe that those products fell outside the treated article exemption from otherwise applicable registration requirements. Finally, because Berkey products are not registered under FIFRA, EPA had reason to believe that their continued sale violated FIFRA’s bar on the sale of unregistered pesticides.

*Pg. 6 of Defendant’s Response (emphasis added)*

36. Plaintiffs note that the EPA did not specifically choose “7. An unqualified claim of “antimicrobial” activity” for support of its actions, though it is arguing that Berkey filters are sold with public health claims. The EPA admits Berkey products are a treated article in their terminated SSURO from vendor B, with registered use of a pesticide to protect the filter from microbes, not treat the water, and rely on qualified antimicrobial claims when issuing the stop orders. But FIFRA does not define pesticides based on mere claims; the EPA’s actions are based on its regulations, which have never before been enforced against non-substance mechanical filters. Thus, the EPA is in clear error of judgment because Berkey products are mechanical treated articles with qualified registered antimicrobial claims unrelated to a substance used to treat water. *See* Doc. 13-1.



37. In the same guidance, the EPA provides examples of treated article exemptions:

Known as the "Treated Articles Exemption," section 152.25(a) provides an exemption from all requirements of FIFRA for qualifying articles or substances treated with, or containing a pesticide, if:

- (1) the incorporated pesticide is registered for use in or on the article or substance, and;
- (2) the sole purpose of the treatment is to protect the article or substance itself.

The exemption gives two examples of treatments that are intended to protect only the treated article or substance itself. In the first case, paint is being protected from deterioration of the paint film or coating. In the second case, wood is being protected from fungus or insect infestations which may originate on the surface of the wood. Pesticides used in this manner are generally classified as preservatives. Other pesticides are incorporated into treated articles because of their ability to inhibit the growth of microorganisms which may cause odors or to inhibit the growth of mold and mildew. Because of this treatment, it is claimed that a fresher and more pleasing surface can be maintained.

To qualify for the treated articles exemption, both conditions stated above must be met. If both are not met, the article or substance does not qualify for the exemption and is subject to regulation under FIFRA.

In recent years, the marketplace has experienced a proliferation of products that are treated with pesticides and bear implied or explicit public health claims for protection against bacteria, fungi and viruses, as well as specific claims against pathogenic organisms which may cause food poisoning, infectious diseases or respiratory disorders. Examples of such articles include toothbrushes, denture cleansers, children's toys, kitchen accessories such as cutting boards, sponges, mops, shower curtains, cat litter, vacuum cleaner bags, pillows, mattresses and various types of finished consumer textiles. In many cases, these products have made public health claims that extend beyond the protection of the article itself, and thus, they do not qualify for the treated articles exemption.

*Notice 2000-1, I, pg. 2*

38. Similarly, the EPA's U.S. EPA, *Pesticide Registration Manual: Chapter 13 - Devices*, Pesticide Registration, (last updated Mar. 1, 2023) states:

"If the product is an instrument or contrivance and claims to control pests through physical or mechanical means, the product is considered to be a device, unless it is a firearm.

Distinctions among devices, pesticides, and pesticide application equipment can be illustrated by comparing products that are outwardly similar but are treated differently under FIFRA. For example, a bait station that is sold by itself to be used in conjunction with other products in the control of insects or rodents is considered to be pesticide application equipment and is not directly regulated under FIFRA, although the labels for registered pesticide products may require them to be used in bait stations in some or all applications.

If the same design of bait station is sold with toxic bait in it (or packaged with it for use in it), the entire product is considered a "pesticide product" and is regulated and labeled as such. If the bait station is sold with a sticky trap inside it (or is packaged with sticky traps that are to be placed inside it), the entire product is a device, and is regulated under FIFRA because it achieves pest control by physical means."<sup>11</sup>

<sup>11</sup> See EPA's Response, Doc. 18, pg. 5; also available at <https://www.epa.gov/pesticides/pesticide-devices-guide-consumers> (last visited September 2, 2023)



39. Berkey Products makes no public health claims based on the silver. As even the EPA had recognized in material collected in its appendix, “The micropores within the Berkey Filters (Black Berkey Elements) are so small that viruses and pathogenic bacteria cannot pass through them.” *See* Doc. 19, pg. 4. The EPA clearly has read that the micropores are responsible for any public health benefits, and not the antimicrobial silver. *See id.* The filter’s silver is registered to protect the filter from nonhuman pathogenic microbes, not to destroy pests in the water. *See* Doc. 13-1. Both conditions are satisfied as required by the EPA’s guidance, the products are a both a mechanical device and a treated article but not a pesticide. Berkey products make no public health claims referencing the silver that extends beyond the protection of the article itself.

40. Further, the issued stop orders quote a foreign website, not under EPA jurisdiction, that clearly states any use of silver is not to treat the water, but to protect the filter. *See* Doc. 14-2, pg. 27-70. No alleged public health claims cited on the stop order refer to the silver but refer to the mechanical aspects of the Berkey products system. *See id.* The EPA is in clear error of judgment by attempting to paint Berkey’s mechanical filters as pesticides. Berkey products contain a registered pesticide as a treated article and make no public health claims relating to the treated article’s uses. *See* Doc. 13-1. Berkey’s success is due to its ability as a mechanical filtration system.

41. As stated multiple times, the silver in Berkey products is to protect the filter, and not to destroy human pathogens. The silver in Berkey products inhibits the growth of Heterotrophic Bacteria within the filter that can affect and clog a filter but are not a human pathogens:

“Heterotrophic microorganisms mostly feed upon dead plants and animals, and are known as decomposers... However, many species of heterotrophic bacteria are also abundant in the environment and are considered normal flora for human skin. The recycling of minerals in aquatic ecosystems, especially in estuaries, is also made possible by heterotrophic bacteria. Although monitored by health officials, the presence of heterotrophic bacteria in public water supplies is seldom considered a public health threat.”<sup>12</sup>

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<sup>12</sup> <https://www.encyclopedia.com/science/encyclopedias-almanacs-transcripts-and-maps/heterotrophic-bacteria>

42. Further, the Berkey products exceed NSF/ANSI standards shown by accredited third-party testing, as required under FIFRA. *See* Doc. 14-4, pg. 2. This satisfies the EPA’s guidance reiterated under the EPA’s “Technical Analysis FIFRA Requirements vs. Certification to National Standards. Doc. 14-4:

**Testing Required Under National Standards and Third-Party Testing**

NSF/ANSI-accredited product standards for water filters are developed through a consumer-driven process that includes industry experts from around the world. These standards are continually being refined to account for new water quality challenges and technologies. Whereas FIFRA requirements are largely based on a manufacturer’s own statement of compliance (self-declaration). Third-party testing and certification provide an independent non-biased way to verify product claims utilizing knowledgeable staff with proven expertise in water filtration technologies.

43. Berkey products exceed NSF/ANSI standards and testing required under national standards and third-party testing. And as stated in the testing results attached to the Complaint as Exh. B-4, para. 26. Berkey filter testing found that no appreciable silver leached into the water. The EPA’s unsupportable claims are thus proven to be scientifically untrue.

44. Berkey products are not pesticides because they do not incorporate any pesticide to destroy pests, nor do they exceed the treated article exemption because they do not make any public health claims regarding the use of the silver for treating the filtered water. Any alleged public health claims refer to nonhuman pathogens such as heterotrophic bacteria, which are seldom considered a public health threat. Berkey products exceed NSF/ANSI standards. This court should enjoin the EPA from enforcing its stop orders and pesticide registration requirements for Berkey products because Berkey products are not pesticides.

***iii. Plaintiffs' Statutory and Constitutional Claims have merit because the EPA violated due process and exceeds statutory authority in clear error by requiring Berkey Products to register as pesticides.***

45. Because Berkey products are not pesticides, this court should enjoin the stop orders and registration requirements as against unconstitutional under due process for lacking proper notice and comment procedures. The EPA's stop orders do not comport with "long-standing regulations and guidance and entailed no change in position." *See Defendant's Memo.*, pg. 19. The EPA's stop orders reflect a change in position from regulating pesticides to regulating mechanical filters that do not contain any pesticides. Those stop orders did not follow required notice and comment procedures under the APA or as required by due process under the 5<sup>th</sup> Amendment. The EPA's stop orders interfere with the settled rights of Plaintiffs and the stop order recipients in their Berkey product business, trust property, and protected intellectual property. *See Doc. 14-4*, pg. 8.

46. The stop orders did not comply with procedural due process requirements under the 5<sup>th</sup> Amendment and for APA notice and comment procedure for final rules. 5 U.S. §§ 553, 554; 7 U.S.C. § 136n. The EPA is still required to comply with 5<sup>th</sup> Amendment and APA due process requirements, which the EPA fully denies:

Plaintiffs are no more likely to succeed under the Fifth Amendment's Due Process Clause. For one thing, their procedural due process arguments merely rehash their earlier claims about EPA's alleged failure to follow notice and comment procedures before issuing a new rule or reversing its prior position. *See Am. Compl.* ¶¶ 156-64. Those claims rest on faulty premises; EPA's actions were based on long-standing regulations and guidance and entailed no change in position. *See supra* pp. 17-18. Moreover, Plaintiffs never clearly define the constitutionally

*Pg. 19 of Defendant's Response (emphasis added).*

642 F. App'x 443, 447 (5th Cir. 2016). Finally, even setting all this aside, EPA has not issued a SSURO to Plaintiffs, and Plaintiffs cite no authority for the proposition that the United States is constitutionally compelled to afford "notice or an opportunity to be heard," Am. Compl. ¶ 160, to every entity claiming a business relationship with the target of a government enforcement action. Plaintiffs are thus unlikely to prevail on their Due Process Clause claim.

*Pg. 27 of Defendant's Response (emphasis added).*

47. Plaintiffs request judicial review to enjoin the EPA from issuing the stop orders and registration requirements in violation of notice and comment requirements of the APA and due process under the 5th amendment. The EPA orders are final agency actions that interfere with Plaintiffs settled rights in selling Berkey products covered by Plaintiffs' license agreements and intellectual property. The stop orders, which were issued without notice and comment, without public hearing, or opportunity for public hearing, will result in the inevitable dissolution of NMCL and irreparably harm the JBS Trust property. *See N.L.R.B.*, 394 U.S. at 772, 777. The basis for the stop orders fails because as a policy interpretive rule it cannot effect Plaintiffs and stop order recipients without first satisfying notice and comment requirements. *Id.*

#### **V. OTHER MATTERS**

38. Respondent may seek federal judicial review of this Order pursuant to section 16 of FIFRA, 7 U.S.C. § 136n.

39. The issuance of this Order shall not constitute a waiver by EPA of its remedies, either judicial or administrative, under FIFRA or any other federal environmental law to address this matter or any other matters or unlawful acts not specified in this Order.

40. This Order shall be effective immediately upon receipt by Respondent or any of Respondent's agents.

*See Stop Orders, Doc. 14-2, pgs. 27-70.*

48. The new rule as issued in the final agency action through the order did not give any notice of the issues, opportunity for responsive pleadings, and no hearing. *Id.* "It should therefore have been put down for the public hearing prescribed by the Act." *See N.L.R.B.*, 394 U.S. at 777; 5

U.S.C.A § 553; *See also Env'tl. Def. Fund, Inc.*, 439 F.2d at 594-95. “The procedure to be followed in ‘adjudication,’ which includes notice of the issues, an opportunity for responsive pleadings, a hearing, and decision, is specified in 5 U.S.C. §§ 554, 556, and 557.” *N.L.R.B.*, 394 U.S. at 772; *See also Mack Trucks, Inc.*, 682 F.3d at 92-6 (D.C. Cir. 2012). If a statement mentioning silver on a non-US website where the statement itself asserts that the silver is used as a non-pesticidal function, then the EPA has no basis for its sudden decision to require registration.

49. These stop orders have caused actual injury and irreparable harm to Plaintiffs and Berkey Int'l, which have been required to lay off employees and stop operations, and are in threat of default on future major contracts. *See Amended Complaint* and Doc. 14-4. Stop orders will continue to be issued if the EPA is not enjoined and NMCL cannot operate with the EPA's change of position reflected in the stop orders. The trustee's fiduciary duties require protection of the JBS Trust property, which is actively and irreparably harmed by injury to royalty payments from stop order recipients and NMCL, and harm to its products covered by intellectual property. *See id.* Plaintiff NMCL and Berkey International, if not all stop order recipients, will go out of business if the stop orders and registration requirements are continued. *See id.* As stated above, the JBS Trust is imperiled with irreparable harm if its trademarks are disused, as a competitor could start using the marks and claim they were abandoned if the JPB Trust is unable to resume sales under that name. The EPA should be enjoined for violating Plaintiffs and stop order recipients due process rights.

**C. Plaintiffs are and will continue to suffer irreparable harm due to stop orders and registration requirements.**

50. As described supra and in the Complaint, Plaintiffs have testified that NMCL will go out of business and the JBS Trust property will continue to be irreparably harmed due to the stop orders and registration requirements. *See Amended Complaint* and Doc. 14-1, -2, -4. Plaintiffs

herein seek to protect the purpose and property of the trust, as well as the continued existence of NMCL. *See id.* Both will cease to exist, as will many other entities, if the EPA is not enjoined from enforcing its erroneous stop orders and registration requirements. *See Id.*

51. Additionally, as stated above, Plaintiffs have standing to protect their business affiliates, who are facing bankruptcy, and end user customers, who will be imperiled by the lack of Berkey filters and be forced to buy knockoffs.

**D. With a reliable history of safe products upon which the public relies, equity calls for an injunction while the Court investigates this challenge to the EPA’s arbitrary and capricious abuse of discretion.**

52. The public interest and balance of equities is in favor of Plaintiff. Plaintiffs and Berkey agents have settled rights in manufacturing, distributing, and selling its mechanical filters without being registered as a pesticide. *See Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564, 577 (1972) (“Property interests, of course, are not created by the Constitution. Rather they are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law—rules or understandings that secure certain benefits and that support claims of entitlement to those benefits.”); *TXI Operations, LP v. City of McKinney, Texas*, 4:20-CV-353, 2023 WL 161942, at \*21 (E.D. Tex. Jan. 11, 2023) (“Indeed, the Supreme Court of Texas rejected the “vested rights” test and adopted a reasonable and settled expectations test.”) *Zaatari v. City of Austin*, 615 S.W.3d 172, 188 (Tex. App.—Austin 2019, pet. denied) (We agree that section 25-2-950 operates to eliminate well-established and settled property rights that existed before the ordinance's adoption.”); and *City of Grapevine v. Muns*, 641 S.W.3d 317, 345 (Tex. App. – Fort Worth 2021, pet. denied).

53. Plaintiffs here assert that the “settled property rights” argument supports the earlier described Ninth Amendment rights, and no court should fear to protect its citizens’ rights.

54. Violations of due process in changed positions of agencies do not serve the public interest.<sup>13</sup> The EPA has changed their position in regulating mechanical water filters with registered pesticides not used for a pesticidal purpose as pesticides without due process. Further, the EPA ignores foreign unauthorized agents selling fake Berkey products, while shutting down real tested Berkey products. Neither equity nor the public interest is served by allowing the EPA to shut down a law-abiding business while relying on claims it did not make in violation of due process. The public interest is not served by agencies who do not respect the right to due process:

SSURO to Plaintiffs, and Plaintiffs cite no authority for the proposition that the United States is constitutionally compelled to afford “notice or an opportunity to be heard,” Am. Compl. ¶ 160, to

*Pg. 27 of Defendant’s Response (emphasis added).*

55. Plaintiffs have served the public for over 20 years without EPA’s new erroneous rule attempting to regulate mechanical filters as pesticides. *See id.* The public interest or balance of equities is not served by shutting down Berkey products and requiring unnecessary and burdensome regulation in violation of due process. *See id.* The public interest and balance of equities are not served by federal agencies, in this case the EPA, that exceed their statutory authority to bring about the inevitable closure of business and absence of products that consumers have wanted for more than 20 years. *See* Doc. 14-4, pg. 8.

## II. ADDITIONAL ARGUMENT

56. Plaintiffs include the Fourth Declaration of James B. Shepherd, attached, which has additional discussion of lost income and the plight of Berkey’s dealers. This information was only recently gathered and is offered as late information that was not available until this week. The

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<sup>13</sup> *See Plaintiff’s Amended Complaint*, ¶ 98 *Idaho Farm Bureau Fed’n v. Babbitt*, 58 F.3d 1392, 1404 (9th Cir. 1995); ¶ 99 *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007) (cleaned up); ¶ 108 *Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 630 (5th Cir. 2001); 5 U.S.C. § 553.



specific sales documentation should eliminate any discussion about the nature of the loss – Berkey’s customers have nothing to buy.

57. With regard to the EPA’s Response, Plaintiffs note that the EPA stated that “Plaintiffs do not allege that ... all royalty payments have ceased.” *Defendant’s Response*, pg. 22. Yet, Plaintiffs did exactly that in Plaintiffs section on irreparable harm:

186. Plaintiffs suffered a real injury when the EPA issued a stop sale order to Berkey International. Due to the SSUROs, royalty payments to JBS Trust for sales of products bearing the IP subject to the licensing agreements of JBS Trust have ceased from NMCL and Berkey International, LLC. Exh. D. Specifically, the license agreement requires Berkey International, LLC

*Plaintiffs’ First Amended Complaint*, pg. 46.

58. Lastly, the EPA wholly failed to respond to Plaintiffs’ argument that the stop orders were issued relying on statements made by foreign entities not under the control of stop order recipients. Nor does the EPA address the fact that even those statements clearly state that any use of silver is not to treat the water, but to protect the filter.

### **III.PRAYER**

59. For all of the reasons stated above, the EPA wrongly issued stop orders against the mechanical Berkey products, resulting in irreparable harm to Plaintiffs. Berkey products are successful mechanical filters with a registered pesticide to protect the filter, not to clean the water. The public has supported Berkey’s mechanical products for over 20 years. Neither the public interest nor equity would serve to shut down production of Berkey’s mechanical products to EPA’s clear error of judgment. Plaintiffs thus reiterate their request for an injunction preventing the enforcement of the subject stop orders and requiring the EPA to cease such further enforcement until this case is concluded or at least the EPA follows the rule-making process of the APA.



Respectfully submitted,

/s/Warren V. Norred

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#### IV. CERTIFICATE OF SERVICE

I certify that on Tuesday, September 5, 2023, I filed this reply with the Clerk of the Court through the ECF system, which will send notification of such filing to the following by email to Andrew Coghlan, Shari Howard, and Mark Walters, at the addresses shown below:

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